

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICANT

: Jackowski et al.

INVENTION

: Biopolymer Marker Indicative Of
Disease State Having A Molecular
Weight Of 1077 Daltons

SERIAL NUMBER

: 09/846,342

FILING DATE

: April 30, 2001

EXAMINER

: Nguyen, Bao Thuy.

GROUP ART UNIT

: 1641

OUR FILE NO.

: 2132.026

RECEIVED

DEC 02 2004

OFFICE OF PETITIONS

CERTIFICATE UNDER 37 CFR 1.8(a)

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DECLARATION UNDER 37 CFR § 1.132

I, George Jackowski, do hereby declare as follows:

1. I am one of the named inventors of the application entitled
**"Biopolymer Marker Indicative of Disease State Having A
Molecular Weight of 1077 Daltons"**, having U.S. Application Serial
No. 09/846,342, filed April 30, 2001.

2. In the Office Action mailed on March 02, 2004, claims 1,
36-43, (as originally presented) were rejected under 35 U.S.C. 112,
first paragraph because the claimed invention allegedly contains
subject matter which was not described in the specification in such

a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims (as currently amended) have been limited to an isolated biopolymer marker having SEQ ID NO:1 (the 1077 dalton marker) useful in methods for determining the presence of the biopolymer marker. The method of the invention as recited in claim 36 involves confirming the presence of the isolated biopolymer marker having SEQ ID NO:1 in the patient sample wherein the presence of the biopolymer marker is indicative of a link to myocardial infarction.

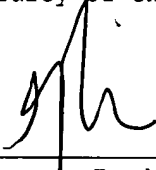
3. The data provided in attached Appendix A was originally filed in Applicant's application no. 09/846,330, now Pub. No. U.S. 2002/0160420, both applications were filed on April 30, 2001. The data further clarifies the identification of SEQ ID NO: 1 in serum samples of patients being evidentiary of myocardial infarction sampled from patients suffering from a variety of disease states, see page A1 of Appendix A.

4. This declaration (including the attached Appendix A) is provided in order to show data obtained from a clinical trial involving over 500 patients suffering from a variety of disease states, see page 32 lines 9 to 15 of Pub. No. U.S. 2002/0160420. The patient specific samples and data are used to formulate a library of proteomic materials having characteristics identifiable with both normal and abnormal physiological conditions or predictive hallmarks thereof. The data on page A1 of Appendix A indicates the patients from which the isolated biopolymer marker

consisting of SEQ ID NO:1 (the 1077 dalton marker) was confirmed are linked to myocardial infarction. This Appendix A does not represent results obtained from additional experimentation. This data was obtained in the original experiments performed at the time of the invention.

The undersigned declares that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the Application or any patent issuing thereon.

Nov 16 2004
Date



George Jackowski

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